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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,204	06/20/2001	Lawrence Restaino	536-3	4612

7590 02/11/2003
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EXAMINER

GUO, LYNDIA T

ART UNIT	PAPER NUMBER
1651	2

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/885,204

Applicant(s)

RESTAINO, LAWRENCE

Examiner

Lynda T Guo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 June 2001.
- 2a) This action is **FINAL**.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____.
 - 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 - * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) Interview Summary (PTO-413) Paper No(s) _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other:

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DETAILED ACTION

Status of the Application

Claims 1-10 of the instant application are pending.

Specification

1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.
2. The disclosure is objected to because of the following informalities: see below.
On page 1, last line, "et..al." should be corrected by removing the two internal period marks.
On page 2, line 4 and page 4, line 8, the word "*Enterobactericeae*" should be fully italicized.
On page 2, line 11, the second period mark after "et al.." should be changed to a comma.
On page 4, lines 17 and 21, "*Enterobacteriaceae*" is a misspelling.
On page 7, Table 1, Supplements section, "novobiocinocin" is a misspelling.
On page 7, last line, there is an extra period mark at the end of the paragraph.
On page 8, Table 2, seventh block, "Domcd" is a misspelling.
On page 8, Table 2, ninth block (*E. hermannii*), "rnm" should be changed to ---mm---.
On page 8, Table 2, last block, "*marcesceens*" is a misspelling.
On page 9, Table 2, last block, "*aeruglnosa*" is a misspelling.
On various pages throughout the instant specification, "galactopyraniside" is a misspelling.

Appropriate correction is required.

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Claim Objections

3. Claims 1, 7 and 9 are objected to because of the following informalities:

Claims 1, 7 and 9, last lines, "quantity_to" should be corrected to remove the underscore mark.

Claim 7 and 9, second to last lines, the "(6)" should be changed to ---(5)---

Claims 3, 8 and 9, "galactopyraniside" is a misspelling.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1, lines 8 and 12, it is unclear whether the "bacteria" recited is the target or non-target bacteria.

Claim 10 recites the limitation "the ingredient for thickening the mixture" in line 3. There is insufficient antecedent basis for this limitation in the claim. It is suggested that the claim be changed to depend from Claim 9 or Claim 7.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monget et al. (USPN 5,434,056).

Claims 1-10 are directed to an isolating plating medium comprising: 1) a carbohydrate metabolizable by the target bacteria (*Salmonella*) selected from the group consisting of 2-Deoxy-D-ribose, xylose, mannitol, dulcitol, sorbitol, L-rhamnose and D-arabitol; 2) a pH indicator dye; 3) a first substrate not reactive with the target bacteria, but is reactive for β -galactosidase and produces a color different from that produced by the pH indicator dye; 4) a second substrate also not reactive with the target bacteria, but is reactive for β -galactosidase and produces a color of "substantially the same color" as that of the first substrate; and 5) a thickener for the medium, preferably agar. The first and second substrates are selected from the group consisting of 5-bromo-4-chloro-3-indoxyl- β -D-galactopyranoside, 5-bromo-6-chloro-3-indoxyl- β -D-galactopyranoside, 3-indoxyl- β -D-galactopyranoside, 6-chloro-3-indoxyl- β -D-galactopyranoside, 4-nitrophenyl- β -D-galactopyranoside, 2-nitrophenyl- β -D-galactopyranoside, 5-iodo-3-indoxyl- β -D-galactopyranoside, 4-methylumbelliferyl- β -D-galactopyranoside and N-methyl-indoxyl- β -D-galactopyranoside. An inhibitor, selected from the group consisting of bile salt, bile salt #3, tellurite, sodium novobiocin and cefsulodin, is optionally added to the medium. Finally, a chromogenic substrate enhancer, selected from the group consisting of isopropyl- β -D-thiogalactopyranoside (IPTG), 1-O-methyl- β -D-thiogalactopyranoside, ethyl- β -D-thiogalactopyranoside, and methyl- β -D-thiogalactopyranoside.

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Monget et al. discloses a medium for the selective detection of *Salmonella*. The medium comprises a chromogenic substrate (preferably 5-bromo-4-chloro-3-indoxyl- β -D-galactopyranoside, but could also be 4-methylumbelliferyl- β -D-galactopyranoside or *p*-nitrophenyl- β -D-galactopyranoside), which is not reactive with *Salmonella* due to its lack of β -galactosidase production. Also in the medium is isopropyl- β -D-thiogalactopyranoside, which enhances the substrate activity by inducing the enzyme, and a pH indicator (neutral red), inhibitors (bile salts), at least one sugar (i.e. carbohydrate) fermented by *Salmonella* chosen from sorbitol, dulcitol, mannitol, inter alia, and agar to solidify the medium. (See Abstract, Column 3, lines 67-68; entirety of Column 4; and entirety of Column 5.) The chromogenic substrate preferred by Monget et al. develops into a color (blue) when hydrolyzed, this color being different from the color developed by the pH indicator, which reacts to become red. The medium of Monget et al. differs from the claimed invention in that Monget et al. does not teach the use of a second substrate not reactive with the target bacteria.

However, the second substrate, as claimed by applicant, is simply another glycon reactive with β -galactosidase. The second substrate differs from the first substrate only in the aglycone attached to the glycon. Additionally, the colors developed from the hydrolysis of the two substrates are "substantially the same". Applicant discloses in the instant Specification on pages 3-4 that "two chromogenic substrates are added to the differentiating medium **to color colonies of non-target bacteria** with essentially the same distinctive color, **a color that contrasts with both the medium and the color** produced by detection of the metabolic activity of *Salmonella* bacteria". Applicant further discloses, "A plurality of chromogenic substrates is desirable to

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differentiate a sample containing a mixture of members of the *Enterobacteriaceae* because a positive reaction between the substrate and non-target bacteria is necessary”.

Applicant has not provided any unexpected results, substantive data or reasoning as to why two chromogenic substrates are required, **especially** since the two substrates are reactive with the **same enzyme** and **produces similar coloration**. As evidenced by the disclosure of Monget et al., supra, one chromogenic β -galactosidase substrate was sufficient to differentiate *Salmonella* from other *Enterobacteriaceae* when used with a pH indicator dye of a different color. Therefore, the addition of two or more chromogenic substrates that have the same reactivity to the same enzyme as claimed by applicant poses no further advantage over adding only one such substrate since it is already established that *Salmonella* are β -galactosidase negative (See Abstract of Monget et al.). The addition of a second substrate, as claimed by applicant, is therefore obviated. The invention as a whole is thus rendered prima facie obvious.

Conclusion

Claims 1-10 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynda T Guo whose telephone number is (703) 605-1200. The examiner can normally be reached on Tue - Fri and alternate Mondays (9:00am - 7:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on (703) 308-4743. The fax phone numbers for

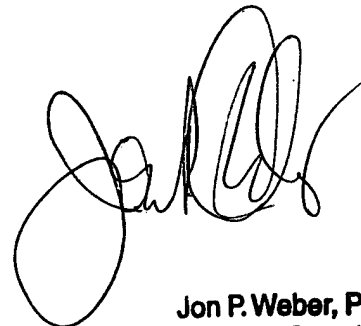
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the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.



Lynda T Guo
Patent Examiner
February 10, 2003



Jon P. Weber, Ph.D.
Primary Examiner